



## Office of Cannabis Management

### Office of Cannabis Management Assessment of Public Comment – Part 130 Cannabis Laboratory Testing Regulations

#### **GENERAL COMMENTS**

**COMMENT:** A commenter stated that the NYS potency tax is going to make it an extreme struggle for the legitimate cannabis market to succeed and compete with the current well-established grey market and requested elimination of the potency tax so that NYS legal cannabis market can be a positive example for the rest of the nation.

**Response:** The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of these comments.

**COMMENT:** The commentor recommended to expand the scope of Shiga-toxin producing E.coli and to reinstate action limits for total viable bacteria counts and total yeast and mold counts.

**Response:** The Office acknowledges these comments, but these comments are outside the scope of the proposed regulations as testing analytes are in policy guidance. The Office will consider the comment for guidance. No changes were made to the proposed regulations as a result of these comments.

#### **DEFINITIONS (130.1) COMMENTS**

**COMMENT:** Comments were received in regard to the definition of True Party of Interest in Section 130.1(w). The commenter stated that only those with 10% or more of interest in a laboratory or sampling firm is a true party of interest, meaning that a person with under 10% of direct or indirect interest is not a true party of interest and is not bound by the requirements of a true party of interest. The commenter further stated that a person with over 5% or less than 10% of direct or indirect interest in a cannabis laboratory is not a true party of interest and that the current definition of a passive investor relates to those who hold less than 5% interest in a licensee with an aggregate ownership interest whose shares are publicly traded. The commenter felt that the requirement of “publicly traded” ownership interest conflicts with the current cannabis industry, as senior stock exchanges (such as the New York Stock Exchange and the NASDAQ) do not allow companies that operate in a federally illegal industry (which would include all Adult-Use License Types) to list. The commenter requested section §130.1(w) be revised, and additional section §130.1(x) should be added

**RESPONSE:** The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

#### **FEES (130.3) COMMENTS**

**COMMENT:** A commenter recommended capping the application change fee referenced in §130.3(b) of the Proposed Regulations to no more than \$200.00 to encourage laboratories to expand their testing capacity.



## Office of Cannabis Management

**RESPONSE:** The Office acknowledges this comment. No changes were made to the proposed regulations as a result of the comment.

### **RENEWAL (130.4) COMMENTS**

**COMMENT:** “§130.4(b) of the Proposed Regulations states that “An application to renew a permit issued under this part shall be filed with the Office not more than six (6) months nor less than four (4) months prior to the expiration thereof. If a renewal application is not filed within four (4) months prior to the expiration thereof, the Board may determine that the permit shall have expired and become void on such expiration date.” This provision currently only allows a two-month window for a renewal application. This window may not be sufficient for renewal applicants and the Office should consider revising this section to either; “shall be filed with the Office not more than seven (7) months nor less than four (4) months prior...” or “shall be filed with the Office not more than six (6) months nor less than three (3) months prior...”

**RESPONSE:** Section 130.4(b) of the Proposed Regulations is providing the timeframe in which an applicant must file their renewal application, not the timeframe in which the Office must approve the renewal application that has been submitted. This allows a two-month window for the applicant to submit the application, and up to six months for the applicant’s renewal to be approved by the Board. No changes were made to the proposed regulations as a result of these comments.

### **LABORATORY REQUIREMENTS (130.7) COMMENTS**

**COMMENT:** A comment was received stating: “§130.7(e)(2) of the Proposed Regulations states that “neither a cannabis laboratory nor its true parties of interest shall have any interest, direct or indirect, including, but not limited to, as a passive investor, landlord, financier or management service provider, to any other license under Article III or Article IV of Cannabis Law.” This prohibition on any Laboratory True Party of Interest, including a passive investor, from being”

**RESPONSE:** The comment was incomplete. No changes were made to the proposed regulations as a result of these comments.

**COMMENT:** Comment was received requesting a definition for “business with limited resources”, which is referenced in both §130.7(g) and §130.7(h).

**RESPONSE:** Both sections refer to “business with limited resources **as determined by the Office**” (emphasis added), which affords the Office the ability to determine what a business with limited resources is.. No changes were made to the proposed regulations as a result of these comments.

**COMMENT:** A commenter expressed concern with the lack of dedicated capacity for research and development (R&D) testing, stating that R&D testing is essential to product development and efficient operations. The commenter further described the benefits of R&D testing, including ability to identify the expected potency of the product, ability to remediate or destroy problematic cannabis before final packaging and testing, helping to save unnecessary costs to licensees.

**RESPONSE:** The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.



### **QA OFFICER QUALIFICATIONS (130.13) COMMENTS**

**COMMENT:** “A commenter expressed concern with the requirements set forth in §130.13(a) stating that this section is unduly burdensome, in that in addition to training or experience, knowledge of the quality system, and knowledge of the analytical methods for which they perform data review, an appointed office must also have a bachelor’s degree in one of the specific degrees listed. The commenter suggested that this be expanded to include any who may possess a Bachelor of Science, along with the other requirements.

**RESPONSE:** The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

### **SAMPLING FIRM REQ (130.16) COMMENTS**

**COMMENT:** A commenter stated that section 130.16(c) does not specify the application process for a Laboratory Sampling Firm and stated that this section should be edited to provide an appropriate method by which applicants may submit an application and general information to be requested in the application.

**RESPONSE:** Application information can be found on the Office of Cannabis Management website under the Labs and Sampling Firm tabs. No changes were made to the proposed regulations as a result of these comments.

### **SAMPLING FIRM LAB REQ (130.19) COMMENTS**

**COMMENT:** A commenter stated that §130.19(k)(1) should be revised to read: “A laboratory sampling firm and its true parties of interest may have an interest in more than one cannabis laboratory and/or sampling firm if they are:” since a cannabis laboratory may already have interest in one sampling firm, even if they do not comply with §130.19(k)(1)(i) or (ii).

**RESPONSE:** The intent of this section is to allow a laboratory sampling firm and its true parties of interest to have an interest in more than one cannabis laboratory and sampling firm. A technical change was made to sections 130.19(k)(1) and 130.7(e)(1) as a result of this comment.

### **SAMPLING OF PRODUCT (130.21) COMMENTS**

**COMMENT:** Comment was received that the Proposed Regulations do not explicitly contemplate final product sampling with the reliance on guidance for this matter. The commenter stated that the packaging requirements mandating that the entire lot of final product from which a sample is collected from be packaged for retail sale prior to laboratory testing does not, in practice, allow for remediation in the case of a microbial failure.

**RESPONSE:** The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

### **REFERENCE LAB (130.28) COMMENTS**



## Office of Cannabis Management

**COMMENT:** “A commenter stated that, within §130.28, there is no mention of who may be chosen for a State Reference Lab and no criteria for which the Office may contract a cannabis laboratory. The commenter suggested revision of this section to more clearly indicate who may be selected as a State Reference Lab, their rights, and precluded activities.”

**RESPONSE:** No changes were made to the proposed regulations as a result of these comments.